

NOT FOR PUBLICATION

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

BAUSCH HEALTH	:	Civil Action No. 21-10057 (SRC)
IRELAND LIMITED, et al.,	:	
	:	
Plaintiffs,	:	OPINION & ORDER
	:	
v.	:	
	:	
MSN LABORATORIES PRIVATE LTD.	:	
et al.,	:	
	:	
Defendants.	:	
	:	

CHESLER, U.S.D.J.

This matter comes before the Court on the three motions *in limine* submitted by Plaintiffs Bausch Health Ireland Limited and Salix Pharmaceuticals, Inc. (collectively, “Bausch”), as well as on the three motions *in limine* submitted by Defendants MSN Laboratories Private Ltd. and MSN Pharmaceuticals Inc., (collectively, “MSN”). All motions have been opposed. For the reasons that follow, Plaintiffs’ motions will be granted and Defendants’ motions will be denied.

I. Plaintiffs’ first motion *in limine*

Plaintiffs ask that the Court enter an Order precluding MSN from “presenting any evidence that refers, directly or indirectly, to filings, transcripts, argument, and other materials” in the Mylan v. Bausch appeal before the Federal Circuit, Case No. 2024-1011. (Pls.’ Br. at 5.) Plaintiffs contend that Defendants have submitted a Supplemental Report from Dr. Arora which refers to materials from this appeal regarding Bausch’s internal testing as evidence of the knowledge of a POSA. The key point, according to Defendants’ brief in opposition, is: “at the

Mylan Oral Argument Mr. Hasford admitted that the Klodt process used in the '786 patent *did, in fact, remove topoisomer impurities from plecanatide.*" (Defs.' Opp. Br. at 1.) The Arora Supplemental Report quotes the transcript of that oral argument as follows:

MR. HASFORD: Respectfully, Your Honor, the – Bausch's own tests showed that the purification process will remove the topoisomers . . ."

(Arora Supp. Rpt. at ¶ 8.) The Arora Supplemental Report expressly cites Mr. Hasford's statement about "Bausch's own tests." Plaintiffs argue, and this Court agrees, that Bausch's internal experimentation is not evidence of the knowledge of the POSA or of the prior art; such evidence has no relevance to any claims or defenses in the instant litigation. Plaintiffs' first motion *in limine* will be granted.

II. Plaintiffs' second motion *in limine*

Plaintiffs ask that the Court preclude MSN from offering evidence or claim construction argument premised on a construction of "trifluoroacetic acid (TFA)" that encompasses both trifluoroacetic acid and trifluoroacetate. In opposition, MSN argues that it is Bausch that has offered a new and late claim construction and infringement theory.

The problem for MSN is twofold. First, after Plaintiffs filed this motion, this Court conducted an expedited Markman proceeding, rejecting MSN's proposed construction of "trifluoroacetic acid (TFA)" and adopting Plaintiffs' proposed construction. This Court has now held that the claim term, "trifluoroacetic acid (TFA)" means trifluoroacetic acid and does not include trifluoroacetate. Second, crucially, MSN overlooks the fact that Plaintiffs now espouse the same construction and infringement contentions that they stated in their originally-filed

infringement contentions.¹ MSN does not mention that Plaintiffs filed infringement contentions that stated that MSN's ANDA product infringed the various claim limitations involving trifluoroacetic acid (TFA) levels because, *inter alia*, the ANDA product contains infringing levels of trifluoroacetic acid. Plaintiffs have not changed their theory of infringement, nor have Defendants shown that Plaintiffs have changed their claim construction of "trifluoroacetic acid (TFA)."²

The Court has now determined that "trifluoroacetic acid (TFA)" means trifluoroacetic acid and does not include trifluoroacetate. Plaintiffs' motion will be granted, and Defendants will be precluded from presenting evidence or argument that relies on their proposed claim construction of "trifluoroacetic acid (TFA)," which this Court has now rejected.

III. Plaintiffs' third motion *in limine*

Although the scope of this motion appeared somewhat broader in Plaintiffs' opening brief, by the end of the reply brief, Plaintiffs narrowed the relief sought on this motion to excluding all references to the McCudden reference at trial. Plaintiffs contend that Defendants did not disclose the McCudden reference in their invalidity contentions; Defendants do not dispute this, but argue in opposition that their expert, Dr. Arora, does not refer to McCudden to advance any new invalidity theory. MSN admits that Dr. Arora cites McCudden in support of the theory that the prior art reference, WO '380, inherently anticipates certain claims at issue. Plaintiffs point

¹ What MSN has shown is that, in 2025, Plaintiffs' expert Dr. Davies began to criticize MSN's use of HPLC for the measurement of trifluoroacetic acid, and that he had not done so in earlier expert reports. MSN has not explained how, given these facts, Federal Circuit law authorizes the Court to deny Plaintiffs' continued reliance on their originally stated, unchanged infringement contentions.

² At most, MSN has pointed to evidence of inconsistent statements from Dr. Davies, which MSN may use to challenge that expert's credibility at trial.

out that, while MSN's invalidity contentions clearly disclosed an inherent anticipation theory based on the WO '972 reference, no such disclosure appears in regard to WO '380 or McCudden.

The Court agrees that, because MSN did not disclose this use of the McCudden reference in its invalidity contentions, it cannot be used at trial. The motion *in limine* will be granted.

IV. Defendants' first motion *in limine*

Defendants move to preclude Plaintiffs' expert, Dr. Davies, from: 1) offering testimony that relies on the theory that the claim term, "trifluoroacetic acid (TFA)," refers to trifluoroacetic acid; and 2) opining that HPLC is an inappropriate method to determine the level of trifluoroacetic acid in a drug substance. Subsequent to the filing of this motion, this Court conducted an expedited Markman proceeding and, as already noted, construed "trifluoroacetic acid (TFA)," to mean trifluoroacetic acid. Dr. Davies will be permitted to present opinions that reflect the Court's claim constructions. As to the second subject, Dr. Davies' opinion about the appropriateness of use of the HPLC method, MSN's argument for exclusion was based on the claim construction dispute that has now been decided in Plaintiffs' favor. The motion will be denied.

V. Defendants' second motion *in limine*

Defendants renewed their motion to exclude Plaintiffs' evidence of infringement based on superseded ANDA and DMF specifications. In short, this problem was previously presented to the Court, and the Court attempted to resolve it by directing MSN to provide product samples to Plaintiffs for testing so that the questions about which ANDA and DMF specifications are relevant to the infringement analysis need not be reached. The parties have reported to the

Court that MSN provided the product samples and Plaintiffs tested them. This has mooted the issues raised in this motion, which will be denied.

VI. Defendants' third motion *in limine*

Defendants move to preclude Plaintiffs' expert, Dr. Davies, "from offering testimony that the headspace gas chromatography (HS-GC) method used to test MSN's samples is a reliable method for testing the TFA content in MSN's samples." (Defs.' Br. at 1.) Defendants' argument on this point is premised on their proposed construction of the claim term, "trifluoroacetic acid (TFA)." Defendants argue that the gas chromatography method does not measure trifluoroacetate unless an additional preparatory step is taken to make trifluoroacetate volatile. Again, the Court has now construed "trifluoroacetic acid (TFA)" and adopted Plaintiffs' proposed construction, which limits the term to trifluoroacetic acid. Because of this, the measurement of trifluoroacetate in product samples is irrelevant. This moots Defendants' challenge to Dr. Davies' use of the gas chromatography method, and the motion will be denied.

For these reasons,

IT IS on this 2nd day of October, 2025

ORDERED that Plaintiffs' first motion *in limine* (Docket Entry No. 346) is **GRANTED**; and it is further

ORDERED that Plaintiffs' second motion *in limine* (Docket Entry No. 347) is **GRANTED**; and it is further

ORDERED that Plaintiffs' third motion *in limine* (Docket Entry No. 350) is **GRANTED**; and it is further

ORDERED that Defendants' first motion *in limine* (Docket Entry No. 348) is **DENIED**;

and it is further

ORDERED that Defendants' second motion *in limine* (Docket Entry No. 353) is **DENIED**; and it is further

ORDERED that Defendants' third motion *in limine* (Docket Entry No. 356) is **DENIED**.

s/ Stanley R. Chesler
STANLEY R. CHESLER, U.S.D.J.